

An International Survey of Deep Brain Stimulation Procedural Steps

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Key Words

Deep brain stimulation • Parkinson's disease • Workflow

Abstract

Background: Deep brain stimulation (DBS) surgery is standard of care for the treatment of certain movement disorders. **Objective:** We sought to characterize the spectrum of steps performed in DBS surgery, at centers around the world where this surgery is performed. **Methods:** We identified the main steps in DBS surgery workflow and grouped these 19 steps into 3 phases (preoperative, operative, and postoperative). A survey tool, informed by a pilot survey, was administered internationally by trained study personnel at high- and low-volume DBS centers. Procedural components, duration, and surgeon motivational factors were assessed. Cluster analysis was used to identify procedural and behavioral clusters. **Results:** One hundred eighty-five procedure workflow surveys (143 DBS centers) and 65 online surveys of surgeon motivational drivers were completed (45% response rate). Significant heterogeneity in technique, operative time, and surgeon motivational drivers was reported across centers. **Conclusions:** We provide a description of the procedural steps involved in DBS surgery and the duration of these

steps, based on an international survey. These data will enable individual surgeons and centers to examine their own experience relative to colleagues at other centers and in other countries. Such information could also be useful in comparing efficiencies and identifying workflow obstacles between different hospital environments.

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Background

Deep brain stimulation (DBS) surgery has become standard of care for the surgical treatment of certain medically refractory movement disorders, including Parkinson's disease (PD), essential tremor (ET), and dystonia. The outcome of DBS for the treatment of these disorders has been reported. Specifically, results of DBS for PD have been published for randomized, controlled trials conducted in the USA [1], the UK [2], and Germany [3], demonstrating superiority in the improvement of quality of life as compared to best medical treatment [1], as well as long-term sustained efficacy of stimulation on most PD motor symptoms [4–6], for generalized and segmental dystonia [7–9] as well as for ET [10–12]. These clinically impressive

outcomes have resulted in the procedure now being performed at many centers in a variety of countries.

Although it is an established and effective treatment for movement disorders, far from all patients eligible for DBS surgery are offered this therapy. Barriers to more widespread adoption of DBS therapy include sometimes unpredictable results, diminishment of patient functional status due to disease progression, possible reluctance of clinicians to refer patients for surgery, shortage of personnel trained in DBS programming, procedural costs, and, in many centers, long waiting lists for DBS surgery. Another potential factor is patient and clinician fear of 'brain surgery', although reported complication rates are low [13]. We hypothesized that a detailed study of the procedural steps involved in DBS surgery and surgeon motivational factors might result in better information for patients and referring physicians about the nature of the procedure and what to expect during surgery, and perhaps allay some of the fears associated with the surgery. No publications have systematically addressed the various ways of performing DBS surgery. We therefore sought to characterize the current spectrum of how DBS procedures are performed in different centers and in different countries around the world. Our hypothesis was that although a detailed analysis of the procedural steps involved in DBS implantation demonstrates a large variety of different approaches, procedural 'clusters' might emerge from the analysis.

The goal of this study was to describe the spectrum of steps performed as part of DBS surgery, and to provide a detailed description of the procedural steps and their duration, at centers around the world where DBS surgery is performed. Publication of these data is intended: (1) to provide patients and referring physicians greater detail about the nature of the procedure and (2) to enable individual surgeons, movement disorder neurologists, and DBS centers to examine their own experience relative to colleagues at other centers.

Methods

Survey Formulation and Survey Tool

The main steps in the DBS surgery workflow were identified by the investigator panel, which consisted of 5 experienced functional neurosurgeons from the USA and Europe, and 1 movement disorders neurologist. These main steps – 19 in total – were then grouped into 3 phases: (1) preparation for the procedure, (2) DBS lead placement in the operating room, and (3) post-DBS lead placement procedures (fig. 1).

A survey tool was then constructed, which included questions about surgical volume, type of practice, diagnosis of the disorder being treated, equipment used, and procedural steps – such as the

use of preoperative imaging, intraoperative electrophysiological confirmation, and intraoperative imaging for confirmation of electrode location. Note that neither research procedures nor procedures that were characterized by respondents as 'irregular' due to procedural mishaps (e.g. equipment broken or unavailable, staff delays, etc.) were included in our analysis.

An initial pilot study of DBS procedural flow was conducted during November and December 2009 in order to test data collection tools, project design, and data analysis methods. This pilot study was conducted during 21 DBS procedures. Study personnel were trained on the administration and completion of this survey and sent to large-volume DBS surgery centers to administer the survey and to provide feedback on its usage. This feedback – which included comments on improving the survey tool as well as identifying any additional procedural steps that might have been omitted by the investigator – was reviewed and incorporated into the final survey instrument. This survey instrument was deployed between April 2010 and March 2011, and a total of 185 surveys were completed. See online supplementary appendix 1 (for all online suppl. material, see www.karger.com/doi/10.1159/000343207) for a copy of the survey instrument.

Survey Site Selection

Survey sites were selected from around the world with the intent of recording as many operations as possible during the study period. We attempted to survey sites representing the spectrum of surgical volume – including high- and low-volume centers – in order to obtain as complete a picture as possible of daily practice.

Procedure Duration

The duration of each identified procedural step and the overall procedural time were documented by study personnel logging the start and end time of each component step.

Motivational Factors

A separate online survey was used to probe surgeon factors as potential drivers for the procedural steps of the operation. These surveys were distributed to neurosurgeons after collection of procedural data and were intended to capture general background information, assess techniques typically employed for key procedural steps (9 in total), and facilitate an understanding of the motivations behind the use of a particular technique. Decision drivers were scored from 1 to 5, with 1 representing the 'least applicable' and 5 the 'most applicable' motivating factor (online suppl. appendix 2). The surgeon factors surveyed were first identified by the investigator panel, and pursued in a pilot study.

In addition to decision factors related to selection of the procedural technique, the questionnaire contained questions aimed at understanding the background of the surgeon and other motivational and behavioral factors. The theoretical foundation for the questionnaire is derived from work by Barbuto and Scholl, which operationalized the assessment of individual behavior [14]. Analysis of the pilot study questionnaire results was used to finalize the wording of the questionnaire, which contained 30 questions addressing critical motivational factors among a larger population of DBS neurosurgeons. Questions about motivation included whether or not the surgeon respondent prioritized the research mission over clinical care, or vice versa.

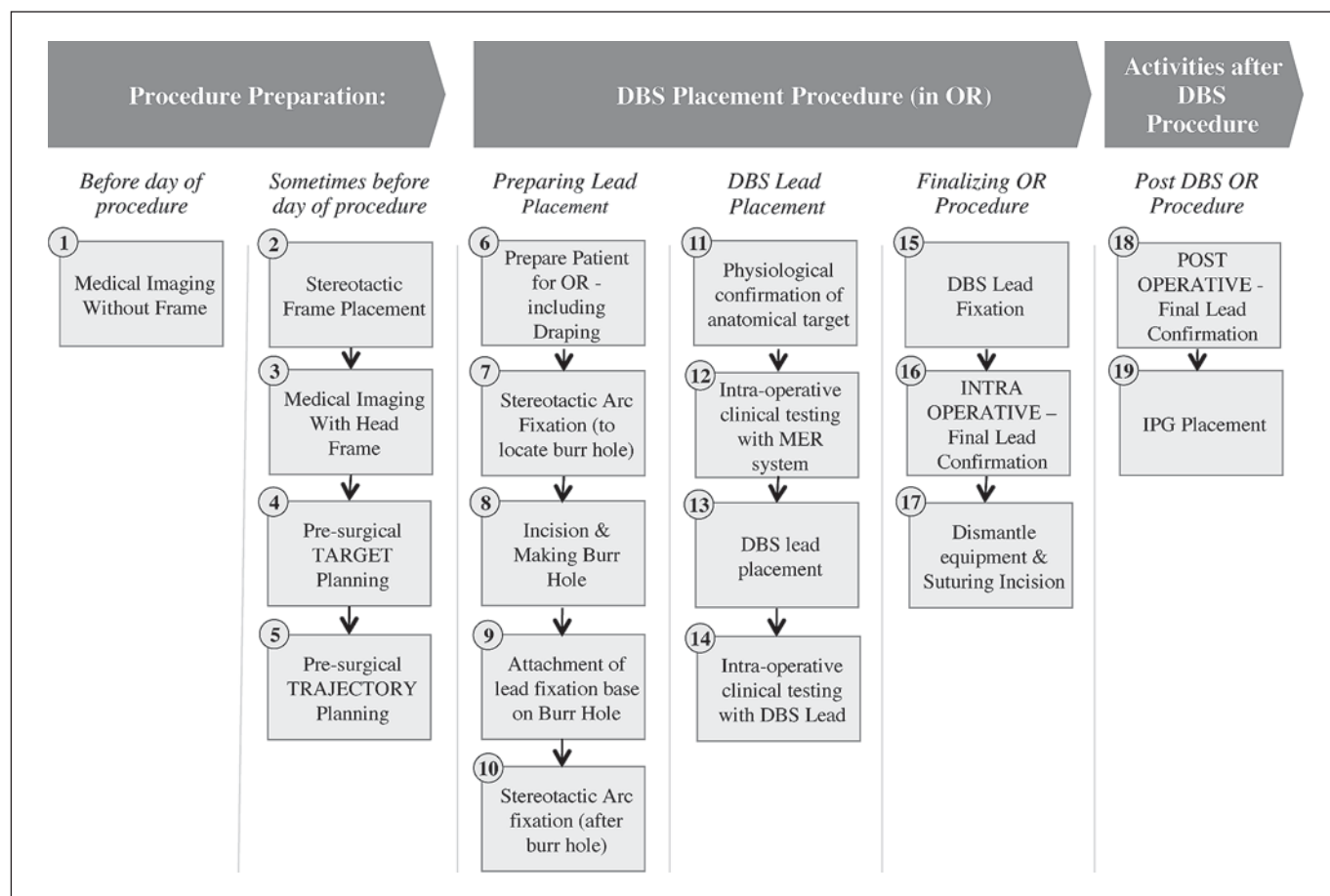


Fig. 1. DBS surgical procedure, broken down into 19 component steps.

Data Analysis

Data compilation and reporting were performed using Excel-based tools (Microsoft, Redmond, Wash., USA). Additionally, Clustan™, a statistical software program, was used to identify procedural and behavioral clusters. Clustan supports the applied analysis process of partitioning larger datasets into homogeneous subsets by grouping closely related cases into tight clusters. These clusters can then be used to construct the underlying model, for segmentation analysis and for exemplification [15].

Results

Summary Statistics

A total of 185 procedure workflow surveys were completed, representing 143 DBS surgery centers (fig. 2). Additionally, surgeons who participated in completion of the procedure workflow survey were invited to fill out the online surgeon motivational driver survey. Sixty-five online surveys of surgeon motivational drivers were utilized.

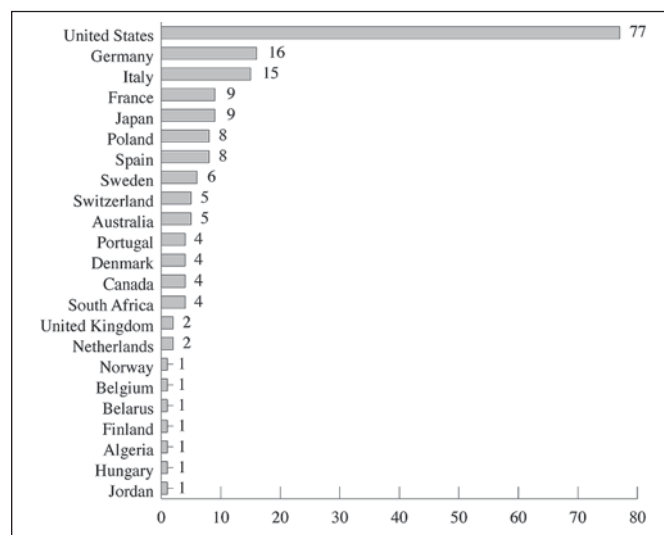


Fig. 2. Number of survey respondents by location of the DBS center (n = 185).

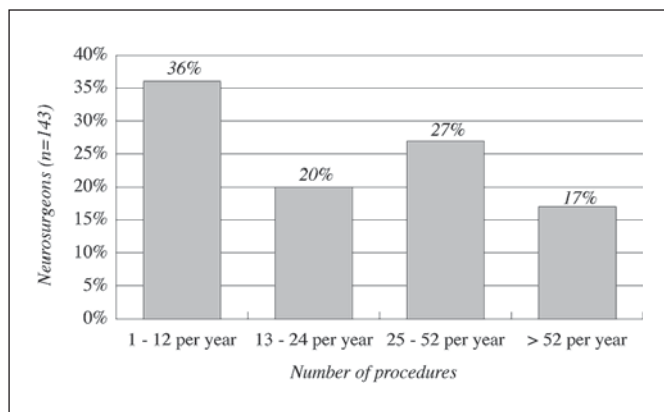


Fig. 3. Reported annual volume of DBS surgeries for participating centers (n = 143).

mately completed. Respondents came from many different countries, including the USA, Canada, Europe, Japan, South Africa, and Jordan. A total of 146 surgeons participated in the survey completion. Additionally, the online Motivational Drivers survey was completed by 45% of potential responders (n = 65).

Survey responses indicated that 36% of neurosurgeons performed fewer than 1 procedure/month, 56% performed fewer than 2 procedures/month, 27% performed 2–4 procedures/month, and 17% performed an average of more than 4 procedures/month (fig. 3).

DBS targets selected for each indication are shown in figure 4, with the majority of procedures carried out for the treatment of PD (n = 131). Interestingly, respondents indicated that 94% of surgeries for PD targeted STN, 3% targeted GPI, and 3% targeted VIM. Of the procedures performed in patients with ET (n = 30), 29 (97%) targeted VIM and 1 (3%) targeted STN (fig. 4).

Procedural Mapping

Survey responses were grouped, by diagnosis of disorder treated, into categories for PD (133), ET (n = 31), and dystonia (21). In each of these categories, 2, 1, and 2 cases, respectively, were reported as research cases and excluded from further analysis. There were a total of 48 unilateral and 137 bilateral DBS procedures reported. Within the former category, 42 surgeries were deemed ‘regular’; within the latter category, 121 procedures were deemed ‘regular’ – meaning nonresearch procedures not characterized by the occurrence of procedural irregularities (e.g. equipment problems, atypical procedural delays, and/or adverse events).

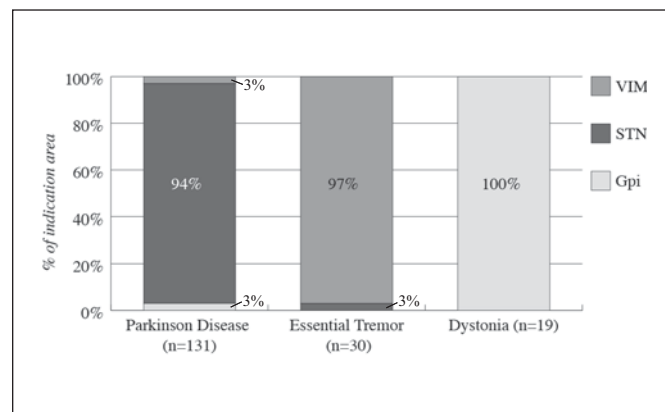


Fig. 4. DBS target used per indication (n = 180, excluding research cases).

Of the total number of surgeries performed for PD (131), 7% were carried out under general endotracheal anesthesia (GETA) versus 56% of surgeries performed for the treatment of dystonia (fig. 5a). The use of conscious sedation during procedures was not surveyed, nor was the rationale for the selection of a particular method of anesthesia. GETA was not used in a single operation for ET. In the case of surgeries for PD, a difference was identified in the use of GETA between large-volume centers characterized by an annual volume of greater than 52 DBS cases/year (26% used GETA) and small-volume centers characterized by a volume of fewer than 12 cases/year (0% used GETA; fig 5b). Surgeries using GETA lasted on average 3:53 versus 4:00 h for surgery without GETA (not statistically significant).

A heat map depicting the percentage of users for each individual technique within the various procedural steps is provided in figure 6. The majority of respondents (69%, n = 125) obtained stereotactic CT imaging of patients in a headframe and co-registered preoperative MRI images to this stereotactic CT. Approximately 83% (n = 149) used a combination of AC-PC-based consensus targeting and direct visualization of target structures (79%, n = 142). The majority of respondents also reported using microelectrode recording to obtain physiological confirmation of the target structure (83%, n = 149). Fluoroscopy was used intraoperatively to confirm lead location by 63% of respondents, and postoperative CT was used for this purpose by 70%. Postoperative MRI was used in the minority of cases to confirm lead location (14%, n = 22).

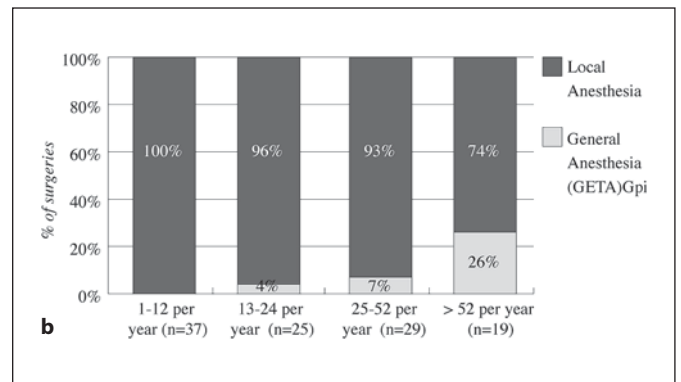
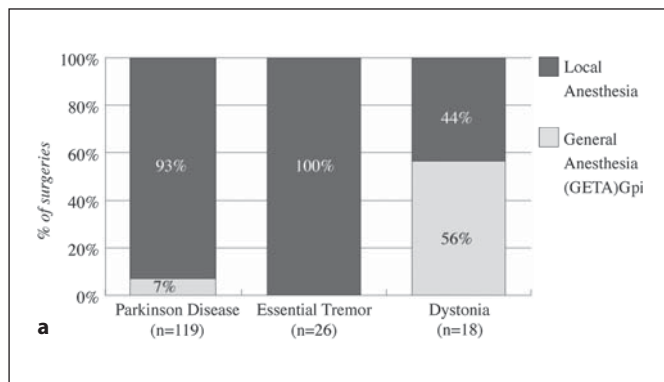


Fig. 5. a Type of anesthesia used for DBS surgeries, by indication. Note that only nonresearch cases ($n = 180$) are included, and 17 cases for which anesthesia type was not recorded are excluded. **b** Type of anesthesia used for DBS surgeries for PD, by DBS center volume ($n = 110$).

Procedural Clusters

Five clusters involving component steps of the overall DBS surgery procedure were identified using Clustan statistical software (fig. 7). These clusters were geographically distributed into predominantly Italian/Polish (cluster 3), German (cluster 4), French/Japanese (cluster 5), and US clusters (clusters 1 and 2; fig. 7; table 1). Cluster 1, representing the USA, Australia, and Spain, was the largest cluster ($n = 45$) and was characterized primarily by the use of a mini-stereotactic frame (25%) and the absence of intraoperative confirmation of lead location (80%). Cluster 2 was comprised of a second US procedural category and Canada. The key difference between clusters 1 and 2 is that the latter was characterized by the use of intraoperative lead confirmation (95%), primarily via fluoroscopy. Cluster 4, representing Germany, comprised the smallest cluster ($n = 9$) and was characterized by the use of the Riechert-Mundiger or RM frame (50%) for stereotaxy, and the use of a mini-plate for DBS lead fixation (54%). Cluster 5 represented France, Japan, and the Nordic countries. This cluster was characterized by the use of MRI-based stereotaxy (79%) and X-ray for intraoperative lead confirmation (54%).

Duration of Procedure and Component Steps

For bilateral procedures in which all steps took place during a single operative day, the total procedural time for steps 2–17 was longest for cluster 3 (Italian/Polish; $n = 14$), at 7:02 h, by a considerable amount, and cluster 1 (USA; $n = 14$) was the shortest at 5:05 h (table 2). Forty-nine percent of DBS procedures involved performing all 4 component surgeries (bilateral DBS electrode place-

Table 1. Geographic distribution of the 5 identified procedural clusters ($n = 146$; 1 case per surgeon)

Countries	Cluster 1 (n = 46)	Cluster 2 (n = 35)	Cluster 3 (n = 33)	Cluster 4 (n = 9)	Cluster 5 (n = 22)
USA	70	71			
Italy	2		30		5
Germany		3	3	89	9
France			3		36
Japan	2	3	3		23
Spain	9	6	3		
Poland	2		15		
Sweden	2	3			9
Canada	2	6			5
Australia	7	3			
Switzerland			6	11	
Portugal			9		
South Africa			9		
UK	2				5
The Netherlands			6		
Denmark	2	3			
Hungary			3		
Jordan					5
Belgium			3		
Norway		3			
Finland					5
Algeria			3		
Belarus			3		
Total	100	100	100	100	100

Values are percents.

Step No.	Step Description	Most frequently used technique			Least frequently used technique	Other/Unknown
1	Medical Imaging - Without Headframe	MRI 83% (n=149)	CT 3% (n=5)	Both MRI & CT (without frame) 2% (n=4)		12% (n=22)
2	Stereotactic Frame Placement	Leksell (Elekta) 51% (n=92)	CRW 29% (n=52)	RM 7% (n=12)	ZD 1% (n=1)	13% (n=23)
3	Medical Imaging - With Headframe	CT Stereotactic 69% (n=125)	MRI Stereotactic 22% (n=40)	Both MRI & CT Stereotactic 4% (n=7)		4% (n=8)
4	Pre-Surgical TARGET Planning	Combi of AC/PC based & direct visual. 79% (n=142)	AC/PC based with respect to MCP 17% (n=30)	Direct visualization targeting 4% (n=7)		1% (n=1)
5	Pre-Surgical TRAJECTORY Planning	Combi of AC/PC based & direct visual. 69% (n=124)	AC/PC based with respect to MCP 10% (n=18)	Direct visualization targeting 8% (n=14)		13% (n=24)
6	Preparing Patient in/ for OR, including Draping	Using 1 Large Drape 64% (n=115)	Using small pieces 29% (n=52)			7% (n=13)
8	Incision & Making Burr Hole	Curved 56% (n=100)	Straight 34% (n=62)	One incision cross both hemisph. 8% (n=15)		2% (n=3)
8B	Specify Burr Hole	14 mm 88% (n=158)	12 mm 3% (n=6)	6 mm 2% (n=4)		7% (n=12)
9	Attachment of Lead Fixation Base (on burr hole)	Medtronic Stimloc 68% (n=123)	Medtronic Cap 12% (n=21)	None (no fixation base used) 12% (n=21)		8% (n=15)
11	Physiological confirmation of anatomical target	Micro-electrode recording set-up 83% (n=149)	No confirmation localization 8% (n=14)	Impedance probe (for target confirmation) 2% (n=4)	Using LFP Techniques 1% (n=1)	7% (n=12)
12	Intra Operative Clinical Testing (with MER system)	Macro Stimulation (using MER Electr.) 62% (n=112)	N/A - no testing before DBS Lead 26% (n=46)			12% (n=22)
13	DBS Lead Placement	Using a Guiding Cannula 62% (n=111)	NOT using a Guiding Cannula 37% (n=67)			1% (n=2)
14	Intra Operative Testing with DBS Lead	Macro Stimulation (using DBS Lead) 51% (n=92)	N/A - no testing with DBS Lead 45% (n=81)			4% (n=7)
15	DBS Lead Fixation	Medtronic Stimloc 70% (n=125)	Medtronic Cap 15% (n=27)	Bone cement 5% (n=9)	Mini plate 7% (n=12)	3% (n=6)
16	INTRA OPERATIVE - Final Lead Confirmation	Fluoroscopy 45% (n=81)	N/A - No Lead Confirmation Done 22% (n=39)	X-Ray 12% (n=22)	CT 6% (n=10)	16% (n=28)
18	POST OPERATIVE - Final Lead Confirmation	CT 61% (n=109)	N/A - No Lead Confirmation Done 13% (n=24)	MRI 12% (n=22)	Fluoroscopy 4% (n=8)	9% (n=17)
19	IPG Implant	Dual Channel IPG 63% (n=113)	One or Two Single Channels 29% (n=52)			8% (n=15)
19B	Specify Location of IPG	Subclavicular 83% (n=149)	Abdominal 10% (n=18)			7% (n=13)



Fig. 6. Heat map of techniques used for each DBS procedural step. Red indicates that more than 65% of surgeons employed a particular technique, orange indicates usage of a technique by 35–64% of surgeons, yellow indicates usage by 10–34%, and white indicates usage by fewer than 10% of surgeons (colors are shown online only).



Fig. 7. Key differences between DBS surgery procedural clusters.

Table 2. Average surgical procedure duration per cluster category

a Duration of OR procedure (steps 6–17)

Cluster	1	2	3	4	5	Overall average
<i>OR duration, h</i>						
Bilateral	3:02 (n = 13)	3:21 (n = 15)	4:09 (n = 16)	3:22 (n = 8)	3:19 (n = 5)	3:30 (n = 57)
Unilateral	1:54 (n = 7)	2:35 (n = 15)	2:27 (n = 4)	(n = 0)	(n = 0)	2:23 (n = 26)

b Duration of the total DBS procedure (steps 2–17)

Cluster	1	2	3	4	5	Overall average
<i>Total duration, h</i>						
Bilateral	5:05 (n = 14)	5:23 (n = 19)	7:02 (n = 14)	5:19 (n = 10)	6:48 (n = 10)	5:52 (n = 67)
Unilateral	3:59 (n = 8)	4:39 (n = 15)	5:08 (n = 5)	(n = 0)	(n = 0)	4:33 (n = 28)

Table 3. Duration of the DBS surgery procedure per surgeon motivational profile

Motivational profile No.	Short profile description	Total duration (steps 1–19), h	Net duration (steps 2–17), h
1	High motivation based on scientific inquiry	5:52	4:59
2	High DBS volume; highly oriented toward patient care	5:13	4:22
3	High DBS volume; evincing a lesser orientation towards patient care	6:31	4:51
4	Minimal motivation by scientific inquiry, low annual DBS surgery volume, and high non-DBS surgical volume	5:18	4:10

ment + bilateral implantable pulse generator/extension cable placement) on a single operative day (fig. 8). Only 13% of cases reported by US sites were *not* staged – in contrast to cases reported by European sites, where the *majority* (66%) of procedures were not staged (fig. 8).

The correlation between greater surgeon DBS volume and shorter duration of procedure is depicted graphically in figure 9. As expected, a statistically significant negative correlation was observed between DBS volume and procedure length (-0.526 , $p = 0.001$). The average time for completing steps 2–17 on a single operative date was 8:45 h, and the shortest duration was 3:50 h. Specific information about time requirements for sequential microelectrode recordings versus multiple simultaneous microelectrode recordings was not obtained.

Surgeon Motivational Factors

A total of 65 surgeons responded to the online survey of motivational factors, intended to determine if these factors correlated with the use of any particular procedural steps or clusters. Four different motivational profiles were identified among respondents: (1) surgeons who reported high motivation based on scientific inquiry, (2) surgeons with a high DBS volume who were highly oriented toward patient care, (3) surgeons with a high DBS volume who evinced a lesser orientation towards patient care, and (4) surgeons who were minimally motivated by scientific inquiry and had a low annual DBS surgery volume and a high non-DBS surgical volume (table 3).

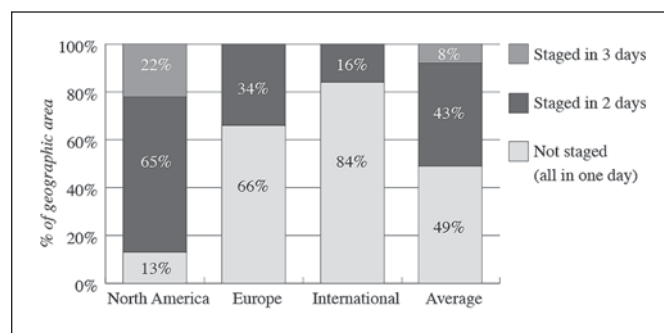


Fig. 8. Staging of component steps of DBS procedure by geographic region.

Discussion

We have provided a detailed description of the procedural steps involved in DBS surgery and the duration of these steps, at centers around the world where DBS surgery is performed. Our hope is that these data will enable individual surgeons and centers to examine their own experience relative to colleagues at other centers and in other countries. No collection of any outcome data – including accuracy of lead placement, clinical efficacy, and adverse events – was intended or obtained in this survey-based study. Rather, the information presented here could be useful for individual surgeons starting out in this field, to gauge their individual time management on a step-by-step basis relative to other practitioners around the world. Such information could also be useful in comparing efficiencies and identifying workflow obstacles between different hospital environments.

Additionally, our analysis revealed profound differences in the procedural workflow between US and European DBS centers, including the fact that procedures occurring in the USA were more likely to be staged than those at European centers, the overall duration of procedures occurring in the USA was shorter than those carried out in European centers, and the majority of procedures in the USA involved the use of a guide canula for placement of the DBS electrode, whereas the majority of procedures performed in Europe did not (fig. 7). It is not clear whether such procedural differences might contribute to differences in patient outcome, and this issue should be considered when reviewing outcome reports.

The use of GPi as a DBS target for the treatment of PD was minimal in our survey. This is interesting since our survey was performed after the publication of results of a

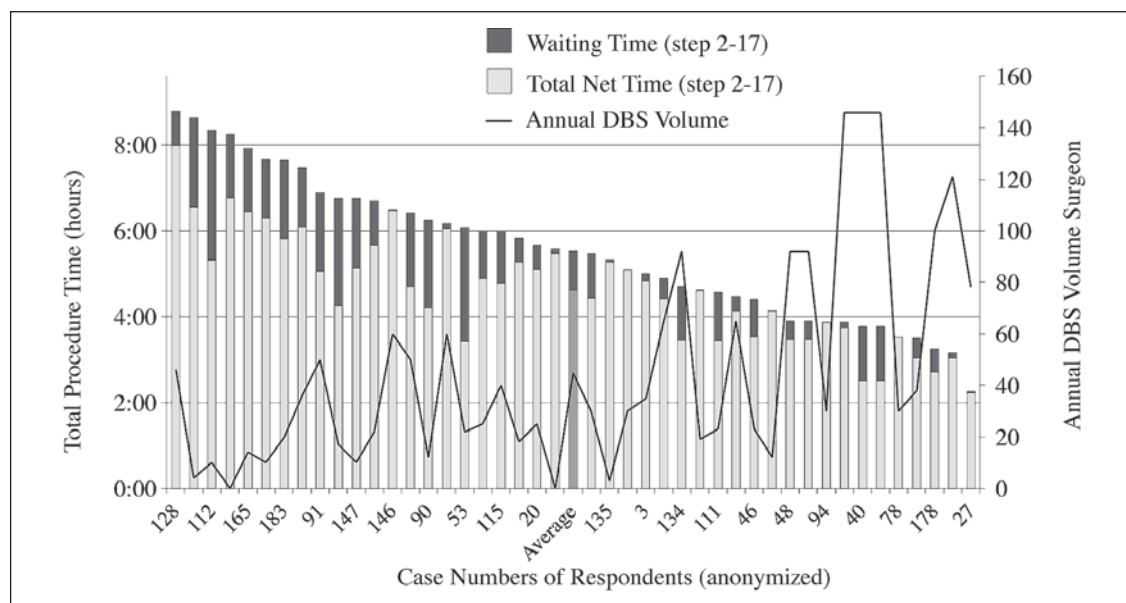


Fig. 9. Duration of DBS procedure (from patient preparation in operating room through closing of incision) and total extra-operative wait time, relative to annual surgeon DBS volume.

large-scale, randomized comparison between GPi and STN DBS for the treatment of PD – a study that demonstrated comparable efficacy for these two targets [16], although with a slightly higher risk of postoperative depression in patients receiving STN DBS. The decision to target STN may be informed by several case series that found the benefit of GPi to attenuate over time [17–20].

One very interesting aspect of this study is the different motivational ‘drivers’ for neurosurgeons performing DBS. Existing published reports about the outcome of DBS surgery are predominantly based on the experience of neurosurgeons at high-volume DBS centers. The procedure, as performed by the larger population of neurosurgeons implanting DBS devices, is possibly quite different and led to our decision to survey low-volume centers as well. The total procedural time was clearly different between high-volume and low-volume DBS implanting centers. Although patient outcome was not assessed in our study, theoretically the risk of infection and other procedure-related complications, as well as patient discomfort, may increase with increasing operative time. It is interesting to note that wait times were longest for surgeons with lower DBS surgery volumes, perhaps reflecting decreased institutional commitment to lower-volume centers, efficiencies of scale associated with larger-volume centers, or greater care taken at lower-volume centers.

Only 13% of cases reported by US sites were *not* staged – in contrast to cases reported by European sites, where the *majority* of procedures were not staged. This finding might reflect differences in US and European physician practice patterns, motivated by differences in clinical rationale and/or insurance reimbursement practices. A correlation between increasing length-of-stay and complication rates has been described in the literature [21, 22]. The possibility that unstaged procedures might be associated with a longer length of stay, could have an impact on the decision to stage the procedure in the USA, where there is increasing scrutiny placed on complication rates [23].

It should be noted that 3.2% of DBS procedures for ET targeted the STN – a target that is not currently approved for this indication by the US Food and Drug Administration. However, this 3.2% represents only one procedure at one surgical center. There is currently limited evidence supporting the use of STN-targeted DBS for ET [24, 25].

Caveats and Pitfalls

This was a survey-based study, with surveys completed by trained study personnel. It was performed prospectively and survey responses were not obtained directly from operative databases or anesthetic records. The response rate to the survey about motivational drivers

within our study, although significantly higher than most physician survey studies [26], was still only 50%, which means that responder bias could have affected the study results.

It should be noted that any given surgeon's 'standard' procedure can change over time and can vary based on the indication for surgery and due to various patient-specific factors.

Finally, it is worth reiterating that the data reported here do not imply that the procedural categories and times reported for each procedural step are appropriate or should be viewed as 'benchmarks'. Nor was this study intended to evaluate which procedural pathways are associated with the optimal benefit-to-side effect profile.

Future Work

With the identification of different procedural clusters within the overall DBS surgical procedure, it might be possible to identify key differences between procedures and construct prospective investigations aimed at evalu-

ating differences in patient outcomes between these procedural clusters. Such an analysis, however, will depend on important factors in addition to the surgical procedure, per se – such as patient selection for DBS for a given diagnosis, and postoperative programming of stimulation and management of medications.

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